

REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated September 11, 2007.

Status of the Claims

Claims 1-20 were pending in the present application. By virtue of this response, claims 1-16, 17 and 18-20 have been cancelled and new claims 21-26 have been added. Accordingly, claims 21-26 are currently under consideration. Allowance of the pending claims is respectfully requested.

With respect to all amendments and canceled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and, moreover, has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

New claims 21-26, are fully supported by the original application. In particular, Claim 21 is supported in original claim 17 and in the specification including at page 2, paragraph [0005]; page 3, paragraph [0011]; page 4, paragraph [0014]; page 7, paragraphs [0026] and [0027]; page 9, paragraph [0035]; page 10, paragraph [0037]; and page 18, paragraph [0058]. Claims 22 and 23 are similarly supported as claim 21, with further support in the specification including at page 2, paragraphs [0005] and [0008]. Claims 24, 25 and 26 are supported by the specification, including at page 6, paragraphs [0020], [0021] and [0022]; and page 7, paragraphs [0023] and [0024].

Specification

The Examiner has objected to the specification disclosure because it states the presence of a total of Figures 1-7, however, only Figures 1-3 appear to be included. Applicants respectfully point out that the specification as filed includes three (3) pages or sheets of

drawings, with Figures 1-3 on the first sheet, Figure 4-6 on the second sheet, and Figure 7 on the third and last sheet of drawings. Applicants have above amended the specification to refer to these three pages of figures as Figures 1, 2 and 3, respectfully, with each of Figures 1 and 2 having multiple parts. Thus, Figure 1 now comprises Fig 1A, Fig 1B and Fig 1C. Similarly, Figure 2 now comprises Figure 2A, 2B and 2C. Figure 7 is now referred to more properly as Figure 3. Applicants submit concurrently herewith replacement drawings reflecting the corrected Figure numbering and lettering. Applicants respectfully request the amendment to the drawings description in the specification and the replacement drawings be accepted and this objection be withdrawn.

Abstract

The Examiner has objected to the Abstract as containing improper content and referring to the merits or speculative aspects of the invention. Further, the Examiner requires that the Abstract mention the 27-hydroxy-7-dehydrocholesterol reductase. Applicants have above amended the Abstract as requested by the Examiner and to comply with the requirements. Applicants respectfully request the Examiner accept the Abstract as above amendment and withdraw this objection.

The Specification Fully Enables the Claimed Invention

The Examiner has rejected claim 17 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the specification does not enable any person skilled in the art to which it pertains, or with which it is most connected, to make and/or use the invention. The Examiner cites the Wands factors in arguing the lack of enablement. In particular, the Examiner asserts that Applicants have provided no working examples of the measuring the activity of 27-hydroxy-7-dehydrocholesterol reductase activity by measuring the level of the reductase or its encoding mRNA. Given the above noted analysis of the factors which the courts have determined are critical in ascertaining whether a claimed invention is enabled, it must be considered that the skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention. Applicants respectfully

disagree. Applicants now present new claims 21-26 which more clearly and particularly set out and claim screening methods. In particular and in accordance with the above claims, the claims as amended and now presented relate generally to screening methods for agents/compounds capable of increasing 27-hydroxy-7-dehydrocholesterol (cholesta-5,7-diene-3 β -27 diol) and/or 27-hydroxy-8-dehydrocholesterol (cholesta-5,8-diene-3 β -27 diol). Applicants submit that this more clearly describes and relates to the desired physiological result, an increase in the 27-hydroxy metabolites of 7-dehydrocholesterol or 8-dehydrocholesterol, and that these methods are fully enabled by the specification, including its teachings and examples, particularly in view of the capabilities and knowledge of the skilled artisan. The 27-hydroxy metabolites of 7-DHC or 8-DHC may be increased by interfering with or inhibiting the 27-hydroxy-7-dehydrocholesterol reductase or stimulating 27-hydroxylase activity. In addition, increasing 7-hydroxylase results in more 7-dehydrocholesterol, thereby providing more substrate for 27-hydroxylation to form 27-hydroxy-7-dehydrocholesterol. Thus, specific such screening methods are now presented, which Applicants assert are fully enabled by the Specification, taking into consideration the extensive and significant skill of the skilled artisan and applying the Wands factors. As noted in the Specification at page 6, paragraphs [0020], [0021] and [0022], the CYP7 genes, CYP7A1 and B1 encode 7 α -hydroxylase. Similarly, as noted at page 2, paragraph [0005], the CYP27 gene encodes 27-hydroxylase. The sequences of each of the CYP7 and CYP27 genes are and were available and public at the time of priority filing of the instant application. Therefore, the screening method of the invention involves identifying agent compounds that increase the 27-hydroxy metabolites of 7-dehydrocholesterol or 8-dehydrocholesterol by assessment of the 27-hydroxylase encoding mRNA, assessment of the 7-hydroxylase encoding mRNA, or assessment of the amount of 27-hydroxy-7-dehydrocholesterol and/or of 27-hydroxy-8-dehydrocholesterol. Each of these screening methods is fully supported in the specification, including as above noted and recited. Applicants respectfully submit that claims 21-26 fully and properly comply with the enablement requirement.

In view of the foregoing remarks and above amendments, Applicants submit that the Examiner's rejection under 35 U.S.C. 112, first paragraph, may properly be withdrawn.

Particularity and Distinctiveness of the Claims

The Examiner has rejected claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention. The Examiner rejects claim 17 asserting that it is unclear from the Specification and claims what enzyme is actually being mentioned. The Examiner further asserts that Applicants do not provide any data in the measurement of 27-hydroxy-7-dehydrocholesterol reductase or its encoding mRNA. The Examiner queries whether “Applicants are claiming to determine the levels of 27 hydroxylase that acts on 7-dehydrocholesterol?”, whether “Applicants are claiming to determine levels of 7-hydroxylase?”, and “what enzyme is being measured, either direct measurement of the enzyme levels, or its encoding mRNA?”. Applicants respond and point out that they now present new claims 21-26 which more clearly and particularly set out and claim screening methods. The claims as presented are directed to screening methods for identifying agent compounds capable of increasing 27-hydroxy-7-dehydrocholesterol and/or 27-hydroxy-8-dehydrocholesterol levels in a cell or an animal or agent compounds capable of increasing the level of 7-hydroxylase in a cell or an animal. The instant claims are more clearly and independently directed to measuring the levels of 27 hydroxylation, mediated by 27 hydroxylase, on 7-dehydrocholesterol or on 8-dehydrocholesterol. In the claims, the levels of 27-hydroxylase encoding mRNA are measured, the levels of 7-hydroxylase encoding mRNA are measured, or the amounts of 27-hydroxy-7-dehydrocholesterol and/or 27-hydroxy-8-dehydrocholesterol are measured. Each of these screening methods is fully supported in the specification, including as above noted and recited. Applicants respectfully submit that claims 21-26 are clear and definite and particularly point out and distinctly claim the subject matter.

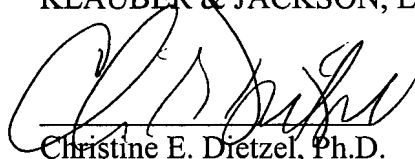
In view of the foregoing amendments and remarks, Applicants submit that the Examiner's rejection is obviated and request that the 35 U.S.C. 112, second paragraph, rejection be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,

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